MiraLax™

Polyethylene Glycol 3350, NF Powder for Solution

DESCRIPTION:
A white powder for reconstitution. MiraLax (polyethylene glycol 3350, NF) is a synthetic polyglycol having an average molecular weight of 3350. The actual molecular weight is not less than 90.0 percent and not greater than 110.0 percent of the nominal value. The chemical formula is $HO(C_2H_4O)_nH$ in which n represents the average number of oxyethylene groups. Below 55°C it is a free flowing white powder freely soluble in water.

MiraLax is an osmotic agent for the treatment of constipation.

CLINICAL PHARMACOLOGY:
Pharmacology: MiraLax is an osmotic agent which causes water to be retained with the stool.

Essentially, complete recovery of MiraLax was shown in normal subjects without constipation. Attempts at recovery of MiraLax in constipated patients resulted in incomplete and highly variable recovery. In vitro study showed indirectly that MiraLax was not fermented into hydrogen or methane by the colonic microflora in human feces. MiraLax appears to have no effect on the active absorption or secretion of glucose or electrolytes. There is no evidence of tachyphylaxis.

CLINICAL TRIALS:
In one study, patients with less than 3 bowel movements per week were randomized to MiraLax, 17 grams, or placebo for 14 days. An increase in bowel movement frequency was observed for both treatment groups during the first week of treatment. MiraLax was statistically superior to placebo during the second week of treatment.

In another study, patients with 3 bowel movements or less per week and/or less than 300 grams of stool per week were randomized to 2 dose levels of MiraLax or placebo for 10 days each. Success was defined by an increase in both bowel movement frequency and daily stool weight. For both parameters, superiority of the 17 gram dose of MiraLax over placebo was demonstrated.

INDICATIONS AND USAGE:
For the treatment of occasional constipation. This product should be used for 2 weeks or less or as directed by a physician.

CONTRAINDICATIONS:
MiraLax is contraindicated in patients with known or suspected bowel obstruction and patients known to be allergic to polyethylene glycol.

WARNINGS:
Patients with symptoms suggestive of bowel obstruction (nausea, vomiting, abdominal pain or distention) should be evaluated to rule out this condition before initiating MiraLax therapy.

PRECAUTIONS:
General: Patients presenting with complaints of constipation should have a thorough medical history and physical examination to detect associated metabolic, endocrine and neurogenic conditions, and medications. A diagnostic evaluation should include a structural examination of the colon. Patients should be educated about good defecatory and eating habits (such as high fiber diets) and lifestyle changes (adequate dietary fiber and fluid intake, regular exercise) which may produce more regular bowel habits.

MiraLax should be administered after being dissolved in approximately 8 ounces of water**,** juice, soda, coffee, or tea.

Information for Patients: MiraLax softens the stool and increases the frequency of bowel movements by retaining water in the stool. It should always be taken by mouth after being dissolved in 8 ounces of water, juice, soda, coffee, or tea. Should unusual cramps, bloating, or diarrhea occur, consult your physician.

Two to 4 days may be required to produce a bowel movement. This product should be used for 2 weeks or less or as directed by a physician. Prolonged, frequent or excessive use of MiraLax may result in electrolyte imbalance and dependence on laxatives.

Laboratory Tests: No clinically significant effect on laboratory tests have been demonstrated.

Drug Interactions: No specific drug interactions have been demonstrated.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long term carcinogenicity studies, genetic toxicity studies and reproductive toxicity studies in animals have not been performed with MiraLax.

Pregnancy: Category C. Animal reproductive studies have not been performed with MiraLax. It is also not known whether MiraLax can cause fetal harm when administered to a pregnant woman, or can effect reproductive capacity. MiraLax should only be administered to a pregnant woman if clearly needed.

Pediatric Use: Safety and effectiveness in pediatric patients has not been established.

Geriatric Use: There is no evidence for special considerations when MiraLax is administered to elderly patients.

In geriatric nursing home patients a higher incidence of diarrhea occurred at the recommended 17 gram dose. If diarrhea occurs MiraLax should be discontinued.

ADVERSE REACTIONS:
Nausea, abdominal bloating, cramping and flatulence may occur. High doses may produce diarrhea and excessive stool frequency, particularly in elderly nursing home patients.

Patients taking other medications containing polyethylene glycol have occasionally developed urticaria suggestive of an allergic reaction.

OVERDOSAGE:
There have been no reports of accidental overdosage. In the event of overdosage diarrhea would be the expected major event. If an overdose of drug occurred without concomitant ingestion of fluid, dehydration due to diarrhea may result. Medication should be terminated and free water administered. The oral LD_{50} is >50 gm/Kg in mice, rats and rabbits.

DOSAGE AND ADMINISTRATION:
The usual dose is 17 grams (about 1 heaping tablespoon) of powder per day (or as directed by physician) in 8 ounces of water**,** juice, soda, coffee, or tea. Each bottle of MiraLax is supplied with a measuring cap marked to contain 17 grams of laxative powder when filled to the indicated line.

Two to 4 days (48 to 96 hours) may be required to produce a bowel movement.

HOW SUPPLIED:
In powdered form, for oral administration after dissolution in water**,** juice, soda, coffee, or tea. MiraLax is available in two package sizes; a 14 oz. container of 255 grams of laxative powder and a 26 oz. container of 527 grams of laxative powder.

The cap on each bottle is marked with a measuring line and may be used to measure a single MiraLax dose of 17 grams (about 1 heaping tablespoon).

Rx only

STORAGE:
Store at 25 degrees C (77 degrees F); excursions permitted to 15-30 degrees C (59-86 degrees F). See USP “Controlled Room Temperature.”

Distributed by Braintree Laboratories, Inc., Braintree, MA 02185

PATIENT INFORMATION

MiraLax™ (Polyethylene Glycol 3350, NF Powder) is a prescription only laxative which has been prescribed by your doctor to treat constipation This product should only be used by the person for whom it was prescribed.

How to take
The dose is 17 grams each day or as directed by physician. It should always be taken by mouth. Measure the dose using the mewing cap (or use one heaping tablespoon of powder), stir and dissolve in a glass (8 oz) of water, juice, soda, coffee or tea. Taking more than the prescribed dose may cause loss of fluid due to severe diarrhea.

How will it work
MiraLax softens the stool and increases the frequency of bowel movements by retaining water in the stool. Your first bowel movement will usually happen in two to four days, although results may vary for individual patients.

How long should I take it
MiraLax achieves its best results when used between one and two weeks. You may discontinue taking the drug after you have had several satisfactory bowel movements. Should unusual cramps, bloating, or diarrhea occur, consult your physician. MiraLax is intended for up to a two week course of therapy. You should not use for a longer time unless directed by your doctor.

Next Steps
After successfully completing the MiraLax therapy (usually between one and two weeks) please discuss with your doctor lifestyle changes which may produce more regular bowel habits (adequate dietary and fluid intake, regular excise).

Who Should NOT take MiraLax
MiraLax should not be used by children. It should not be used by pregnant women unless prescribed by a physician.

Side Effects/Drugs Reactions
Occasionally, MiraLax may cause nausea, stomach fullness wing, diarrhea and/or gas. Do not take if you have symptoms such as nausea, vomiting, abdominal pain or distention, which may be due to bowel obstruction On rare occasions hives and skin rash have bees reported which are suggestive of an allergic reaction If you get an allergic reaction you should discontinue the medication and call your doctor.

If you are allergic to polyethylene glycol, do not use this drug.